IN THE U.S. PATENT AND TRADEMARK OFFICE

APPLICANT: Toyoaki Suzuki et al.

APPLICATION NO.: 10/582,100

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FOR: Multi-Chamber container

GROUP: 1782

EXAMINER: Yager, James C

D E C L A R A T I O N

Honorable Commissioner of Patents and Trademarks

Washington, D.C. 20231

Sir,

I, Toyoaki Suzuki, resident of c/o Research and Development Center, Fujimori Kogyo Co., LTD., 1-10-1, Sachiura, Kanazawa-ku, Yokohama-shi, Kanagawa-ken, Japan do hereby declare that:

1. I was graduated from Department of Pharmacy, College of Science and Technology, Nihon University, Japan in March 1988. Since April 1988, I have been

employed by Fujimori Kogyo Co., LTD., the assignee of the above-identified application. I have been engaged in research and development of packaging materials mainly regarding packaging of medicine having non-absorbability in the laboratory of the company.

2. I am one of the named inventors of the above-identified application and hence, am familiar with the subject matter disclosed in said application.

3. In order to show the feature of the present invention, I conducted the following experiments.

[Experiments]

[Example 7]

A sheet 2 with a total thickness of 200 μm, which consists of a surface layer with a thickness of 20 μm, an intermediate layer with a thickness of 140 μm, and a heat-sealable layer with a thickness of 40 μm, was prepared by multi-layer coextrusion from the following materials.

Material for the surface layer: A composition composed of component (a) defined below and propylene homopolymer in a ratio of 9:1.

Material for the intermediate layer: A composition composed of component (a) defined below and metallocene plastomer ("Kernel" from Japan Polychems, Inc.) having a tensile modulus of 100 MPa in a ratio of 8:2.

Material for the heat-sealable layer: A composition composed of component (a) defined below and component (b) defined below in a ratio of 6:4.

[Component (a)]

A reactor-type propylene-based TPO (Thermoplastic Olefin Elastomer) (from Mitsubishi Chemical Corporation), which gives such a specific ratio of the amount of elution measured by the temperature rising elution fractionation method at temperatures ranging from 0° C to 140° C with o-dichlorobenzene as a solvent that the ratio of the amount of elution at 0° C to the whole amount of elution

is 30 wt%, and the ratio of the amount of elution at 60° C to 90° C to the whole amount of elution is 5 wt%.

[Component (b)]

A reactor-type propylene-based TPO (Thermoplastic Olefin Elastomer) (from Mitsubishi Chemical Corporation), which gives such a specific ratio of the amount of elution measured by the temperature rising elution fractionation method at temperatures ranging from 0° C to 140° C with o-dichlorobenzene as a solvent that the ratio of the amount of elution at 0° C to the whole amount of elution is 5 wt%, and the ratio of the amount of elution at 60° C to 90° C to the whole amount of elution is 55 wt%.

[Example 8]

The Sheet 3 was prepared as well as the sheet 1 or sheet 2 except using the following components (a) and (b).

[Component (a)]

A reactor-type propylene-based TPO (Thermoplastic Olefin Elastomer) (from Mitsubishi Chemical Corporation), which gives such a specific ratio of the amount of elution measured by the temperature rising elution fractionation method at temperatures ranging from 0° C to 140° C with o-dichlorobenzene as a solvent that the ratio of the amount of elution at 0° C to the whole amount of elution is 15 wt%, and the ratio of the amount of elution at 60° C to 90° C to the whole amount of elution is 10 wt%.

[Component (b)]

A reactor-type propylene-based TPO (Thermoplastic Olefin Elastomer) (from Mitsubishi Chemical Corporation), which gives such a specific ratio of the amount of elution measured by the temperature rising elution fractionation method at temperatures ranging from 0° C to 140° C with o-dichlorobenzene as a solvent that the ratio of the amount of elution at 0° C to the whole amount of elution is 10 wt%, and the ratio of the amount of elution at 60° C to 90° C to the whole amount of elution is 40 wt%.

The elution properties of components (a) and (b) of the sheets 2 and 3 are shown in the Table 3 with the parallel description of the elution property of components (a) and (b) of the sheet 1.

Table 3

Component	Temperature	Elution property*1 by TREF method (wt%)		
		Sheet 1	Sheet 2	Sheet 3
(a)	0°C	23	30	15
	60-90°C	8	5	10
(b)	0°C	7	5	10
	60-90°C	50	55	40

*1:The ratio of the amount of elution at 0°C or 60-90°C to the whole amount of elution.

[Evaluations]

[Properties after sterilization]

Thus, each of the obtained sheets 2 and 3 was heat-sealed at 200°C and 0.5 MPa for 4 seconds to form the peripheral sealed part and the port sealed part. Then it was heat-sealed at 160°C and 0.2 MPa for 2 seconds to form the weakly sealed part that separates the inside of the container into two compartments. Thus, container 7 was obtained from sheet 2 and container 8 was obtained from sheet 3, respectively.

Each of the resulting compartmented containers 7 and 8 having two compartments divided were evaluated as follows.

In the containers 7 and 8, each of two compartments was filled with 1 liter of distilled water for injection and then sealed. The containers 7 and 8 underwent sterilization at 121° C for 30 minutes. In the containers 7 and 8, the weakly sealed parts did not rupture after sterilization, and they were possible to join the compartments together easily by pressing with hand.

The containers 7 and 8 were found to have total light transmittance of 91 %, 89 %, haze value of 12 %, 13 % and tensile modulus of 230 MPa, 245 MPa respectively, which were measured immediately after sterilization at 121° C for 30 minutes.

The container properties after sterilization of the containers 7 and 8 are shown in the Table 4 with the parallel description of the container properties after sterilization of the container 1.

Table 4

Container Properties	Container 1	Container 7	Container 8
Light transmittance(%)	90	91	89
Haze value(%)	13	12	13
Tensile modulus(MPa)	220	230	245

[Heat sealing test]

Each of the sheets 2 and 3 was also evaluated for the same heat sealing test as the paragraph [0151] of Saito et al. (US 2004/0137177 A1) that a pressure of 4kgf/cm^2 and a sealing time of 5 seconds is kept substantially unchanged, heat sealing temperature (surface temperature of heat-sealing mold) was changed from 110 to 220° C at intervals of 10° C, thereby forming 12 kinds of sealed portions, the heat-sealed sheet was placed in an autoclave and heat-pressurized at 121° C for 60 minutes, thereafter, the test pieces were prepared in a width of 15 mm from the sheet and tested to measure a heat-seal strength thereof in a 180° peel strength with pulling speed of 200 mm/min.

The results using sheets 2 and 3 are shown in Table 5 with the parallel description of the results using the sheet 1 and Saito's sheet.

In table 5, hatching means a range of controllable heat-sealing temperature to form the weakly seal part based on the same manner as Saito et al. US' 177 as shown at paragraph [0080] that the strong sealed portion has a 180° peel strength of usually 3 to 6 kgf/15mm, and the weak sealed portion has a 180° peel strength of usually 0.2 to 2kgf/15mm.

Table 5

Heat-sealing Temperature (℃)	Seal strength (kgf/15mm)			
	Sheet 1	Sheet 2	Sheet 3	Saito's Sheet
110	0.05	0.04	0.05	0.10
120	0.12	0.14	0.15	0.20
130	0.21	0.18	0.20	0.50
140	0.30	0.34	0.30	1.20
150	0.42	0.45	0.40	3.50
160	0.60	0.60	0.56	4.30
170	1.10	1.00	1.00	4.80
180	1.70	1.80	1.60	5.00
190	2.00	2.20	2.00	4.20
200	3.60	3.40	3.40	4.00
210	4.30	4.80	4.70	4.00
220	4.20	5.10	5.90	4.20

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated this 6th day of December, 2010

Toyoaki Segawa